



DOCKET NO.: ADOL-0721

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In Re Application of:**

**Roland E. Dolle**

**Application No.: 10/719,627**

**Filing Date: November 21, 2003**

**For: CARBOXAMIDE AND AMINO DERIVATIVES AND METHODS OF THEIR  
USE**

**Confirmation No.: Not Yet Assigned**

**Group Art Unit: Not Yet Assigned**

**Examiner: Not Yet Assigned**

DATE OF DEPOSIT: *January 23, 2004*

I HEREBY CERTIFY THAT THIS PAPER IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL, POSTAGE PREPAID, ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE UNITED STATES PATENT AND TRADEMARK OFFICE, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

*Elizabeth A. McLoud*

TYPED NAME: Elizabeth A. McLoud

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of

the above identified application as set forth in § 1.491, before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

- In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with  the first or  second After Final Submission, therefore:
  - Certification in Accordance with § 1.97(e) is attached; or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:
  - Certification in Accordance with § 1.97(e) is attached;
  - or
  - The fee of \$180.00 as set forth in § 1.17(p) is attached.
- In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).
- Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- Copies of references listed on the attached Form PTO-1449 are enclosed herewith
- Copies of references listed on the attached Form PTO 1449 are not required to be submitted pursuant to the June 30, 2003 recent revisions to 37 CFR § 1.98(a)(2)(i).

EXCEPT THAT:

- In view of the voluminous nature of references **11, 20, 21, 22 and 25**, and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
  - Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior Application No.

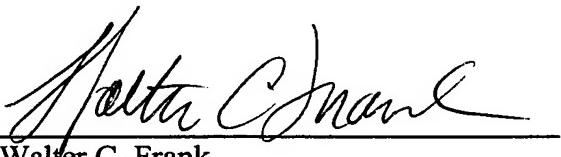
, filed

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

- The relevance of those listed references which are not in the English language is as follows:
- English language abstracts have been provided for references 33, 35, 43 and 44 which are not in the English language.

Date:

*Jan 23, 2004*

  
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**Form PTO-1449 Modified**

List of Patent and Publications  
Cited by Applicant  
(Use several sheets if necessary)

U.S. Department of Commerce  
Patent and Trademark Office

Docket No.  
ADOL-0721

Application No.  
10/719,627

Applicant  
Roland E. Dolle

Filing Date  
November 21,  
2003

Group  
Not Yet Assigned

Confirmation No.  
Not Yet Assigned

**U. S. PATENT DOCUMENTS**

<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>
	26	5,354,863	10/11/94	Dappen, et al.	546	35
	27	6,200,978	03/13/01	Maw, et al.	514	254.05
	28	6,436,959 B1	08/20/02	Carson, et al.	514	326
	29	2003/0069241 A1	04/10/03	Mchardy, et al.	514	241

**FOREIGN PATENT DOCUMENTS**

<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Translation</b>	
					<b>YES</b>	<b>NO</b>
	30	WO 93/15062	08/05/93	PCT		
	31	WO 95/04734	02/16/95	PCT		
	32	WO 95/31464	11/23/95	PCT		
	33	WO 96/22276	07/25/96	PCT	X abstract	
	34	WO 97/10216	03/20/97	PCT		
	35	WO 01/46192 A1	06/28/01	PCT	X abstract	
	36	WO 02/094794 A1	11/28/02	PCT		
	37	WO 02/094810 A1	11/28/02	PCT		
	38	WO 02/094811 A1	11/28/02	PCT		

**EXAMINER****DATE CONSIDERED**





<b>Form PTO-1449 Modified</b>		Docket No. ADOL-0721	Application No. 10/719,627
List of Patent and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Roland E. Dolle	
U.S. Department of Commerce Patent and Trademark Office		Filing Date November 21, 2003	Group Not Yet Assigned
		Confirmation No. Not Yet Assigned	
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	<b>1</b>	Baker, T.J., et al., "Novel reagents and reactions for drug design," <i>Pure Applied Chem.</i> , <b>2000</b> , 72(3), 347-354	
	<b>2</b>	Bhargava, H.N., et al., "Effect of nitric oxide synthase inhibition on tolerance to analgesic action of D-Pen <sup>2</sup> , D-Pen <sup>5</sup> enkephalin and morphine in the mouse," <i>Neuropeptides</i> , <b>1996</b> , 30(3), 219-223	
	<b>3</b>	Bilsky, E.J., et al., "SNC 80, A selective, nonpeptidic and systemically active opioid delta agonist," <i>J. of Pharmacology &amp; Experimental Therapeutics</i> , <b>1995</b> , 273(1), 359-366	
	<b>4</b>	Bilsky, E.J., et al., "Effects of naloxone and D-Phe-Cys-Tyr-D-Trp-Arg-Thr-Pen-Thr-NH <sub>2</sub> and the protein kinase inhibitors H7 and H8 on acute morphine dependence and antinociceptive tolerance in mice," <i>J. Pharmacol. and Exp. Ther.</i> , <b>1996</b> , 277(1), 484-490	
	<b>5</b>	DiMaio, J., et al., "Structure-activity relationships of cyclic enkephalin analogs," <i>Life Sciences</i> , <b>1982</b> , 31, 2253-2256	
	<b>6</b>	Dondio, G., et al., "Central & peripheral nervous systems; Non-peptide delta opioid agonists and antagonists," <i>Exp. Opin. Ther. Patents</i> , <b>1997</b> , 7(10), 1075-1098	
	<b>7</b>	Dorland's Illustrated Medical Dictionary, 27 <sup>th</sup> Ed., <i>W.B. Saunders Co., Phila., PA</i> , <b>1988</b> , page 816	
	<b>8</b>	Dorland's Illustrated medical Dictionary, 27 <sup>th</sup> Ed., <i>W.B. Saunders Co., Phila., PA</i> , <b>1988</b> , page 375	
	<b>9</b>	Dourish, C.T., et al., "Enhancement of morphine analgesia and prevention of morphine tolerance in the rat by the cholecystokinin antagonist L-364, 718," <i>Eur. J. Pharmacol.</i> , <b>1988</b> , 147, 469-472	
	<b>10</b>	Galligan, J.J., et al., "Cerebral delta opioid receptors mediate analgesia but not the intestinal motility effects of intracerebroventricularly administered opioids," <i>J. Pharm. and Exp. Ther.</i> , <b>1984</b> , 229(3), 641-648	
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

*	<b>11</b>	Greene, T.W., et al., Protective Groups in Organic Synthesis, 2 <sup>nd</sup> Ed., <i>Wiley &amp; Sons</i> , 1991
	<b>12</b>	Jain, K.K., "A Guide to Drug Evaluation for Chronic Pain," <i>Emerging Drugs</i> , 2000, 5(2), 241-257
	<b>13</b>	Livingston, E.H., et al., "Postoperative Ileus," <i>Digestive Diseases &amp; Sciences</i> , January 1990, 35(1), 121-132
	<b>14</b>	Lord, J.A.H., et al., "Endogenous opioid peptides: multiple agonists and receptors," <i>Nature</i> , June 9, 1977, 267, 495-499
	<b>15</b>	Mao, J., et al., "Oral administration of dextromethorphan prevents the development of morphine tolerance and dependence in rats," <i>Pain</i> , 1996, 67, 361-368
	<b>16</b>	Mosberg, H.I., et al., "Bis-penicillamine enkephalins possess highly improved specificity toward $\delta$ opioid receptors," <i>Proc. Natl. Acad. Science USA</i> , October 1983, 80, 5871-5874
	<b>17</b>	Moulin, D.E., et al., "The analgesic efficacy of intrathecal D-Ala <sup>2</sup> -D-Leu <sup>5</sup> -enkephalin in cancer patients with chronic pain," <i>Pain</i> , 1985, 23, 213-221
	<b>18</b>	Neugebauer, W., et al., "147. Solid-phase synthesis of C-terminal peptide amino alcohols," <i>Helvetica Chimica Acta</i> , 1989, 72, 1319-1323
	<b>19</b>	Nichols, M.L., et al., "Enhancement of the antialloodynic and antinociceptive efficacy of spinal morphine by antisera to dynorphin A (1-13) or MK-801 in a nerve-ligation model of peripheral neuropathy," <i>Pain</i> , 1997, 69, 317-322
*	<b>20</b>	Physician's Desk Reference, 1999

EXAMINER	DATE CONSIDERED
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\* A copy of these references will not be forwarded to the U.S. Patent and Trademark Office since they are believed to be too voluminous and easily obtainable by the Examiner.



JAN 26 2004

Sheet 3 of 5

<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office	Docket No. ADOL-0721	Application No. 10/719,627
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**OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

*	<b>21</b>	Remington's Pharmaceutical Sciences, <i>Mack Publishing Co., Easton, PA, 1980</i>
*	<b>22</b>	Resnick, J., <i>Am. J. of Gastroenterology, 1997, 92, 751</i>
	<b>23</b>	Resnick, J., "Delayed gastric emptying and postoperative ileus after nongastric abdominal surgery: Part II," <i>Am. J. of Gastroenterology, 1997, 92(6), 934-940</i>
	<b>24</b>	Su, T-P, "Delta opioid peptide [ <i>D</i> -Ala <sup>2</sup> , <i>D</i> -Leu <sup>5</sup> ]enkephalin promotes cell survival," <i>J. of Biomed. Sci., 2000, 7, 195-199</i>
*	<b>25</b>	Weinheim, <i>Analgesics Wiley-VCH, Verlag GMbH &amp; Co. KgaA, Buschmann, H., et al. (Eds.), 2002</i>

<b>EXAMINER</b>	<b>DATE CONSIDERED</b>
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